

LED Headlight System Battery Charger accessory to LED Headlight System / Integra LifeSciences Corp. (8/14)

Reason/Information:

Integra LifeSciences issued a voluntary recall on the following materiel. Reason: LED battery chargers may prematurely fail and will not charge the LED battery as intended.

Disposition/Instructions:

Integra initiated a voluntary recall on 11 June 2014 to consignees that have been shipped affected product lots of Integra LED Battery Chargers. The written notifications were delivered to CONUS consignees by traceable courier service and OCONUS consignees by traceable email or facsimile.

The consignee notification:

----Advises customers of the nature of the issue and the potential for an adverse patient consequence.

----Advises customers to review inventory and how to determine if customers have affected battery chargers.

----Advises customers to immediately stop the use or distribution of any affected product lot numbers.

----Requests customers identify and report to Integra if customers do or do not have any unexpired affected product lots.

----Advises customers replacements battery chargers will be shipped for any affected products customers affirm are in their possession and how to return affected product.

For general questions call 800-431-1123.

Note 1:

Materiel distributed from 08 October 2013 to 11 March 2013 and manufactured from 12 September 2012 to 05 March 2013.

Item Information:

NSN (FSC-NIIN): 6515-NS1
Part Number: 90520US
Nomenclature: LED HEADLIGHT W/BATTERY & AC/DC POWER SUPPLY
UI: EA
Manufacturer: INTEGRA BURLINGTON MA, INC.
Distributor: INTEGRA LIFESCIENCES CORP.

LOT / SN:

IE123610

IE123710 IE123810 IE123910

IE124010	IE124110	IE124210	IE124310
IE124410	IE124510	IE124610	IE124710
IE124810	IE124910	IE125010	IE125110
IE125210	IE130110	IE130210	IE130310
IE130410	IE130510	IE130610	IE130710
IE130810	IE130910	IE131010	

NOTES:

NOTE 1:

Product Identification #90523

NOTE 2:

Unit found CONUS

NSN (FSC-NIIN): 6515-NS2

Part Number: 90520EU

Nomenclature: LED HEADLIGHT W/BATTERY & AC/DC POWER SUPPLY

UI: EA

Manufacturer: INTEGRA BURLINGTON MA, INC.

Distributor: INTEGRA LIFESCIENCES CORP.

LOT / SN:

IE123610

IE123710 IE123810 IE123910

IE124010	IE124110	IE124210	IE124310
IE124410	IE124510	IE124610	IE124710
IE124810	IE124910	IE125010	IE125110
IE125210	IE130110	IE130210	IE130310
IE130410	IE130510	IE130610	IE130710
IE130810	IE130910	IE131010	

NOTES:

NOTE 1:

Product Identification #90523

NOTE 2:

Unit found OCONUS

NSN (FSC-NIIN): 6515-NS3

Part Number: 90520UK

Nomenclature: LED HEADLIGHT W/BATTERY & AC/DC POWER SUPPLY

UI: EA

Manufacturer: INTEGRA BURLINGTON MA, INC.

Distributor: INTEGRA LIFESCIENCES CORP.

LOT / SN:

IE123610

IE123710 IE123810 IE123910

IE124010	IE124110	IE124210	IE124310
IE124410	IE124510	IE124610	IE124710
IE124810	IE124910	IE125010	IE125110
IE125210	IE130110	IE130210	IE130310
IE130410	IE130510	IE130610	IE130710

IE130810 IE130910 IE131010

NOTES:

NOTE 1:

Product Identification #90523

NOTE 2:

Unit found OCONUS

NSN (FSC-NIIN): 6515-NS4

Part Number: 90520AU

Nomenclature: LED HEADLIGHT W/BATTERY & AC/DC POWER SUPPLY

UI: EA

Manufacturer: INTEGRA BURLINGTON MA, INC.

Distributor: INTEGRA LIFESCIENCES CORP.

LOT / SN:

IE123610

IE123710 IE123810 IE123910

IE124010 IE124110 IE124210 IE124310

IE124410 IE124510 IE124610 IE124710

IE124810 IE124910 IE125010 IE125110

IE125210 IE130110 IE130210 IE130310

IE130410 IE130510 IE130610 IE130710

IE130810 IE130910 IE131010

NOTES:

NOTE 1:

Product Identification #90523

NOTE 2:

Unit found OCONUS

Service/Additional Instructions:

CONSIGNEES: US Air Force Academy 4102 Pinion Dr Ste 1008 Colorado Springs CO 80840;
Walter Reed National Military Medical Center 8901 Wisconsin Ave Bethesda MD 20889; Naval
Medical Center 54 Lewis Minor St Bldg 250 Portsmouth VA 23708

ARMY:

Army activities in possession of subject equipment are required to report the status of their work to the USAMMA NMP NLT:30-JUL-2014.

For Questions or Comments, contact: USAMMA NMP

Email: usarmy.detrick.medcom-usamma.mbx.nmp-mmqc@mail.mil

Phone (COMM): 301-619-6648/4464/3170

Phone (DSN): 343-6648/4464/3170

POC Contact Information:

USAMMC-E

Email: usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil
Phone (COMM): 011-49-6331-86-7118/7181
Phone (DSN): 495-7118
Fax: 6218

US ARMY

Email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil
Phone (COMM): 301-619-4300
Phone (DSN): 343-4300
Fax: 301-619-4468

US AIR FORCE

Email: afmoa.sgalc@us.af.mil
Phone (COMM): 301-619-4170
Phone (DSN): 343-4170
Fax: 301-619-2557

US NAVY

Email: MMQC2@MED.NAVY.MIL
Phone (COMM): 301-619-3085
Phone (DSN): 343-3085
Fax: 301-619-2473

Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In Afi 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.